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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0769; FRL-9937-22]

Naphthalene Acetates; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the naphthalene acetate group in or on pomegranate. Interregional Research Project Number 4 (IR-4) requested the tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0769, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution

Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0769 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0769, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL-9921-94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8310) by IR-4, IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ. The petition requested that 40 CFR 180.155 be amended by establishing tolerances for residues of a family of plant growth regulators, the naphthalene acetates, in or on pomegranate at 0.05 parts per million (ppm). That document referenced a summary of the petition prepared by AMVAC Chemical Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the naphthalene acetates including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with the naphthalene acetates follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In this regulatory action, 1-naphthaleneacetic acid is a species of chemical that includes several similar compounds: Naphthaleneacetamide (NAA acetamide), naphthaleneacetic acid, potassium naphthaleneacetate (NAA potassium salt), ammonium naphthaleneacetate (ammonium NAA), sodium naphthaleneacetate (NAA sodium salt), and ethyl naphthaleneacetate (NAA ethyl ester). These chemicals are assessed as a single group and are collectively referred to as the naphthalene acetates (NAA). Hereafter, NAA will be used to refer to the entire naphthalene acetate group. These chemical compounds are structurally related,

metabolized to the acid form (by both plants and animals), and are eliminated from the body as glycine and glucuronic acid conjugates within 36 to 48 hours after exposure. EPA has concluded that toxicity testing on any of these compounds should serve for all members of this group of chemicals.

In general, NAA sodium salt was the most toxic form in sub-chronic and chronic studies. Repeated exposure in oral toxicity studies resulted in decreased body weights and body weight gains accompanied by decreased food consumption. The major target organs of sub-chronic and chronic oral exposure were the liver, stomach, and lung. Others symptoms of toxicity from oral exposure included decreased hematocrit and hemoglobin, reduced red blood cell (RBC) count in rats and dogs, and hypocellularity of the bone marrow in dogs. In contrast to oral exposures, NAA ethyl ester was the most toxic chemical species when administered dermally, inducing epidermal hyperplasia and hyperkeratosis, sebaceous gland hyperplasia, and dermal inflammation. The NAA sodium salt required a 10-fold higher dose to elicit similar dermal effects and no dermal effects were noted in the NAA acetamide exposure. Systemic toxicity was not a consequence of dermal exposure to any of the tested naphthalene acetates.

Developmental and offspring toxicity was linked to NAA sodium salt exposure but was not a common observation for the entire naphthalene acetate group. Developing rats exhibited decreased fetal weight and minor skeletal changes and were more susceptible to NAA sodium salt toxicity than the maternal rats. Skeletal defects and variants were observed in rabbit fetuses after exposure to NAA sodium salt in the developmental rabbit study; however these effects only occurred at doses that also compromised maternal health. Offspring toxicity from NAA sodium salt manifested as reduced litter survival and pup weight throughout lactation in two

generations. These effects coincided with reduced body weight in both parental generations indicating the adults and their young were equally susceptible to NAA sodium salt.

Carcinogenicity studies of NAA acetamide in mice and NAA sodium salt in rats and mice are considered adequate for the evaluation of the oncogenicity of the NAA group. In these three studies the tested NAA compounds were not carcinogenic in mice or rats.

Specific information on the studies received and the nature of the adverse effects caused by NAA as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document, "Naphthalene Acetate. Human Health Risk Assessment for a Proposed New Use on Pomegranate" at pp. 31 in docket ID number EPA-HQ-OPP-2014-0769.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general

principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for NAA used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for NAA for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	An acute RfD for the general population or any population subgroups was not selected because no effect attributable to a single exposure was observed in animal studies		
Chronic dietary (All populations)	NOAEL= 25 mg/kg/day UF_A = 10x UF_H = 10x	Chronic RfD = 0.25 mg/kg/day	Co-critical Dog Studies with NAA Na salt: Subchronic Toxicity Chronic Toxicity

	FQPA SF = 1x	cPAD = 0.25 mg/kg/day	Subchronic [1] LOAEL = 150 mg/kg/day based on GI tract lesions and hypocellularity of the bone marrow **Subchronic NOAEL= 25 mg/kg/day** **Chronic LOAEL = 75 mg/kg/day** based on stomach lesions in 75% of the males and slight sinusoidal histiocytosis in the liver of 50% of the males
Adult Oral Short-term (1-30 Days)	NOAEL= 25 mg/kg/day UF_A = 10x	LOC = 100	Co-critical Dog Studies with NAA Na salt: Subchronic Toxicity Chronic Toxicity

	UF_H = 10x FQPA SF = 1x		Subchronic LOAEL = 150 mg/kg/day based on GI tract lesions and hypocellularity of the bone marrow **Subchronic NOAEL= 25 mg/kg/day** **Chronic LOAEL = 75 mg/kg/day** based on stomach lesions in 75% of the males and slight sinusoidal histiocytosis in the liver of 50% of the males Chronic NOAEL = 15 mg/kg/day
Inhalation Short-Term (1-30 days)	[2]NOAEL= 25 mg/kg/day	LOC = 1000	Co-critical Dog Studies with NAA Na salt:

	UF_A = 10x UF_H = 10x [3]FQPA SF = 10x		Subchronic Toxicity Chronic Toxicity Subchronic LOAEL = 150 mg/kg/day based on GI tract lesions and hypocellularity of the bone marrow **Subchronic NOAEL= 25 mg/kg/day** **Chronic LOAEL = 75 mg/kg/day** based on stomach lesions in 75% of the males and slight sinusoidal histiocytosis in the liver of 50% of the males Chronic NOAEL = 15 mg/kg/day
Cancer	Not carcinogenic based on rats and mice bioassays. Not mutagenic.		

LOC = level of concern. Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. Mg/kg/day = milligram/kilogram/day. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (c = chronic). RfD = reference dose.

[1]The NOAEL/LOAEL used to set endpoints for the co-critical dog studies are in bold.

[2]Inhalation absorption is assumed to be equivalent to oral absorption.

[3]FQPA SF for inhalation accounts for the lack of an inhalation study.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to NAA, EPA considered exposure under the petitioned-for tolerance as well as all existing NAA tolerances in 40 CFR 180.155. EPA assessed dietary exposure to NAA in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for NAA; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), Version 3.16, which incorporates 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). DEEM default processing factors were used to modify the tolerance values. As to NAA residues levels in food, tolerance-level residues and 100 percent crop treated (PCT) assumptions were applied for all affected crops.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that NAA does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for NAA. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for NAA in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of NAA. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Tier 1 (Rice Model) Estimated Drinking Water Concentrations (EDWCs) in surface and groundwater for NAA were used in the dietary exposure assessment. The EDWCs were calculated using the Tier 1 surface water aquatic model First Index Reservoir Screening tool (FIRST) and the Tier I/II groundwater model Pesticide Root Zone Model Ground Water (PRZM

GW), in Tier I mode. Accordingly, the EDWCs of NAA for chronic exposures for non-cancer assessments are estimated to be 65.1 parts per billion (ppb) for surface water and 646 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 646 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

NAA is currently registered for root dip and sprout inhibition applications to ornamentals, which could result in residential exposures. There is a potential for short-term oral and inhalation exposures to residential handlers, resulting from loading and applying NAA. Though there is potential for dermal exposures for residential handlers, no dermal endpoint was selected due to the lack of systemic toxicity up to the limit dose (1,000 milligram/kilogram/day (mg/kg/day)). There are no residential uses for NAA that result in incidental dermal or oral exposure to children. The rooting compounds are applied by holding the plant and dipping the roots into solution. Very little exposure is expected from this use. Sprout inhibitors are applied by spray or paint brush/roller after pruning trees, or by spraying near the base of the tree after pruning root suckers. There is very little potential for post-application exposure to NAA for adults or children based on the residential use pattern; therefore, residential post-application exposure is not expected, nor is intermediate- or long-term exposure based on the intermittent nature of applications by homeowners.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found NAA to share a common mechanism of toxicity with any other substances, and NAA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that NAA does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/culmative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be

safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is low concern and no residual uncertainty for pre- and/or postnatal toxicity resulting from exposure to the naphthalene acetates. Clear NOAELs and LOAELs were established for the developmental and offspring effects and the points of departure selected for all exposure scenarios are protective of these effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for the oral and dermal routes of exposure but retained a 10X for the inhalation route of exposure. That decision is based on the following findings:

i. The toxicity database for NAA is complete, except for a subchronic inhalation toxicity study. EPA is retaining a 10X FQPA SF for the inhalation route of exposure however, as discussed in Unit III.C.3, the EPA only expects short-term inhalation exposures to residential handlers, resulting from loading and applying NAA. Therefore, there is no concern for increased susceptibility in infants and children via the inhalation route. EPA waived the requirements for the acute and subchronic neurotoxicity studies.

ii. There is no indication that NAA is a neurotoxic chemical based on the available studies in the database, and EPA determined that there is no need for acute and subchronic developmental neurotoxicity studies or additional UFs to account for neurotoxicity.

iii. The endpoints selected from the co-critical dog studies are protective of the effects observed in the rat developmental, rabbit developmental, and rat reproduction studies. Therefore, the potential for increased susceptibility in infants and children is low.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to NAA in drinking water. Based on the discussion in Unit III.C.3., regarding limited residential use patterns, exposure to residential handlers is very low and EPA does not anticipate post-application exposure to children or incidental dermal or oral exposures to toddlers resulting from use of NAA in residential settings. These assessments will not underestimate the exposure and risks posed by NAA.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, NAA is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to NAA from food and water will utilize 15% of the cPAD for infants < 1 year old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of NAA is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Using the exposure assumptions described in this unit for short-term exposures, short-term aggregate risk was estimated for combined oral and inhalation exposure in adults applying naphthalene acetate products with a paint-airless sprayer. This is considered the worst case scenario for the aggregate risk assessment. Endpoints selected for the short-term adult oral exposure and inhalation exposure were based on common effects and could therefore be combined in the aggregate assessment.

The EPA calculated an aggregated risk indices (ARI) to combine inhalation and oral exposures to adults. This resulted in an ARI greater than 1. An ARI value greater than 1 is not of concern to EPA, therefore, aggregate exposure to residential handlers is acceptable.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, NAA is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, NAA is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to NAA residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, a high performance liquid chromatography (HPLC) method using fluorescence detection (Method NAA– AM–001) and a similar method (Method NAA–AM–002), is available to enforce the tolerance expression for NAA in plant commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the

United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There is no established Codex MRL for NAA use on pomegranate.

V. Conclusion

Therefore, a tolerance is established for residues of NAA in or on pomegranate at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a

proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 3, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.155, add to the table in alphabetical order an entry for "pomegranate" to read as follows:

§ 180.155 1-Naphthaleneacetic acid; tolerance for residues

(a) * * *

Commodity	Parts per million

* * * * * * *	
Pomegranate	0.05
* * * * * * *	

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[FR Doc. 2015-31309 Filed: 12/11/2015 8:45 am; Publication Date: 12/14/2015]